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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K081300

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:	Siemens Healthcare Diagnostics Inc. P.O. Box 6101 Newark, DE 19714-6101
Contact Information:	Siemens Healthcare Diagnostics Inc. P.O. Box 6101 Newark, DE 19714-6601 Attn: Pamela A. Jurga Tel: 302-631-8891
Date of Preparation:	May 7, 2008

2. Device Name / Classification

- Dimension Vista® HDLC Flex® reagent cartridge (K3408A) / Class I

3. Identification of the Predicate Device

- Dimension® AHDL Flex® reagent cartridge (K073072)

FDA Guidance Document(s):

- "Replacement Reagent and Instrument Family Policy" - 12/11/2003
- "Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable - Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA Staff " - 4/25/2006

4. Device Description(s):

Dimension Vista® HDCL Flex® reagent cartridge is a pre-packaged in-vitro diagnostic test method (assay) that is specifically designed to be used on the Dimension Vista® Integrated system, a floor model, fully automated microprocessor-controlled, integrated instrument system. The Dimension Vista® system was previously cleared with seven associated test methods

(K051087). This Special 510(k) is submitted for a packaging modification to in-vitro diagnostic devices that have been cleared under the 510(k) process for use on Dimension® clinical chemistry systems. The packaging change is to allow use on the Dimension Vista® system.

The reagents contained in the Dimension Vista® Flex® reagent cartridges are the same as those contained in the Flex® reagent cartridges manufactured for the Dimension® clinical chemistry systems, another family of Siemens analyzers. The packaging modification does not affect the intended use of the devices, nor does it alter the fundamental scientific technology of the device.

The HDLC assay measures serum HDL cholesterol levels directly without the need for sample pretreatment or specialized centrifugation steps, using a two reagent format. In the first reaction, chylomicrons, VLDL and LDL form water soluble complexes with dextran sulfate in the presence of magnesium sulfate. These complexes are resistant to the polyethylene glycol (PEG)-modified cholesterol esterase (CE) and cholesterol oxidase (CO) that react with HDL cholesterol. In the second reaction, in the presence of oxygen, the HDL cholesterol is oxidized to Δ-4-cholestenone and hydrogen peroxide. The generated hydrogen peroxide then reacts with 4-aminoantipyrine (4-AAP) and N-(2-hyroxy-3-sulfopropyl)-3,5-dimethoxyaniline (HSDA) in the presence of peroxidase to form a colored dye that is measured using a bichromatic (600/700 nm) technique. The color intensity of the dye is directly proportional to the serum HDL-C concentration.

5. Device Intended Use:

The HDLC method is an *in vitro* diagnostic test for the quantitative measurement of high density lipoprotein cholesterol (HDL-C) in human serum and plasma on the Dimension Vista® System. Measurements of HDL-C are used as an aid in the diagnosis of lipid disorders (such as diabetes mellitus), various liver and renal diseases, and in the assessment of risk for atherosclerosis and cardiovascular disease.

6. Medical device to which equivalence is claimed:

Substantial Equivalence:

This product is substantially equivalent to other HDL-C test systems, such as the Dimension® AHDL Flex® reagent cartridge (K073072).

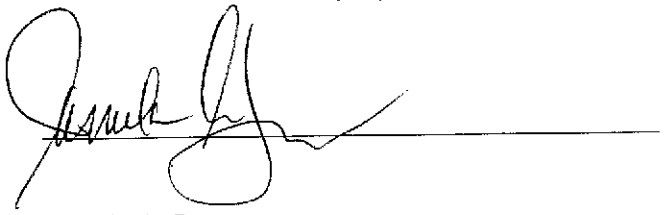
Comparison to Predicate Device:

Both the Dimension Vista® HDLC Flex® reagent cartridges and the predicate Dimension® AHDL Flex® reagent cartridges contain prepackaged reagents in flexible plastic cartridges. A comparison of the important similarities and differences between the two Flex® cartridges is provided in the following table.

Feature	Dimension Vista® HDLC Flex® reagent cartridge (K3408A)	Dimension® analyzer AHDL Flex® reagent cartridge (DF48B) k073072
Reagents	Prepackaged, 12 well plastic Flex® reagent cartridges	Prepackaged, 6 well plastic Flex® reagent cartridges

Intended Use	The HDLC method is an *in vitro* diagnostic test for the quantitative measurement of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on the Dimension Vista® system. Measurements of HDL-C are used as an aid in the diagnosis of lipid disorders (such as diabetes mellitus), various liver and renal diseases and in the assessment of risk for atherosclerosis and cardiovascular disease.	The AHDL method is an *in vitro* diagnostic test for the quantitative measurement of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on the Dimension® clinical chemistry system. Measurements of HDL-C are used as an aid in the diagnosis of lipid disorders (such as diabetes mellitus), various liver and renal diseases and in the assessment of risk for atherosclerosis and cardiovascular disease.
Final concentration of sample/reagent ratio in test milieu	Same as Dimension® analyzer	As described in k073072
Reagent form	Liquid	Liquid
Total test contained in each Flex® cartridge	120 tests	30 tests
Calibration	90 days	90 days
Sample Type	Serum and lithium or sodium heparin plasma	Serum and lithium or sodium heparin plasma
Reportable Range	3-150 mg/dL	3-150 mg/dL
Sample Size	1.3 µL	3 µL
Measurement	Bichromatic endpoint @ 600 and 700 nm	Bichromatic endpoint @ 600 and 700 nm
Certification	Evaluated by and met the certification criteria of the Cholesterol Reference Method Laboratory Network (CRMLN)	Evaluated by and met the certification criteria of the Cholesterol Reference Method Laboratory Network (CRMLN)

Conclusion:
The proposed Siemens Dimension Vista® HDLC method (K3048A) and the predicate Dimension® AHDL method (DF48B) (k073072) are substantially equivalent in design, principle, and performance. They have the same intended use and indications for use. Comparative testing also demonstrates substantially equivalent performance.



Pamela A. Jurga

Regulatory Affairs & Compliance Manager

May 7, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Siemens Healthcare Diagnostics, Inc.
c/o Pamela A. Jurga,
Regulatory Affairs and Compliance Manager
Glasgow Business Community
P.O. Box 6101, Mail Stop 514
Newark, DE 19714-6101

Re: k081300
Trade/Device Name: Dimension Vista® HDLC Flex® reagent cartridge
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, subject to 21 CFR sec. 862.9(c)(4)
Product Code: JHM
Dated: June 23, 2008
Received: June 24, 2008

Dear Ms. Jurga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081300

Indications For Use:

The HDLC method is an *in vitro* diagnostic test for the quantitative measurement of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on the Dimension Vista® system. Measurements of HDL-C are used as an aid in the diagnosis of lipid disorders (such as diabetes mellitus), various liver and renal diseases and in the assessment of risk for atherosclerosis and cardiovascular disease.

Prescription Use __√__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081300